

Applicant: Teva Pharmaceuticals (Pty) Ltd	Product: NUVIGIL 50; 150 & 250 mg tablets
Date of Registration: 20 April 2021 NUVIGIL 50 mg: 48/1.1/1129 NUVIGIL 150 mg: 48/1.1/1130 NUVIGIL 250 mg: 48/1.1/1131	Each tablet contains 50; 150 or 250 mg armodafinil respectively
SAPHRA approved: 15.11.2024	

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S5

NUVIGIL 50 mg (Tablets)

NUVIGIL 150 mg (Tablets)

NUVIGIL 250 mg (Tablets)

Armodafinil

NUVIGIL 50 mg contains 35,9 mg sugar (lactose monohydrate)

NUVIGIL 150 mg contains 107,7 mg sugar (lactose monohydrate)

NUVIGIL 250 mg contains 179,5 mg sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking NUVIGIL.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor pharmacist, nurse or other healthcare provider.
- NUVIGIL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. WHAT NUVIGIL IS AND WHAT IT IS USED FOR
2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NUVIGIL
3. HOW TO TAKE NUVIGIL
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE NUVIGIL
6. CONTENTS OF THE PACK AND OTHER INFORMATION

Amendments have been compiled according to SAHPRA recommendations, and the PIL is free of typographical and grammatical errors.

*Initialed by:
Avisha Gordhan
(M. Pharm)*

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1. WHAT NUVIGIL IS AND WHAT IT IS USED FOR:

NUVIGIL is a prescription medicine used to improve wakefulness in adults who are very sleepy due to the following diagnosed sleep disorder:

- narcolepsy.

NUVIGIL will not cure this sleep disorder. NUVIGIL may not stop all your sleepiness. Follow your doctor’s advice about using other treatments.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NUVIGIL:

Do not take NUVIGIL:

- if you are hypersensitive (allergic) to armodafinil, modafinil or to any of the other ingredients of NUVIGIL.
- if you have high blood pressure or an irregular heartbeat.
- if you are pregnant or may become pregnant.

Warnings and precautions:

Take special care with NUVIGIL:

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Serious rash requiring hospitalisation and discontinuation of treatment has been reported with the use of NUVIGIL. NUVIGIL should be discontinued at the first sign of rash, unless the rash is clearly not medicine related. Discontinuation of treatment may not prevent a rash from becoming life-threatening or permanently disabling or disfiguring.

You should discontinue NUVIGIL treatment and immediately contact your healthcare professional if any signs or symptoms suggesting angioedema or anaphylaxis (e.g., swelling of face, eyes, lips, tongue or larynx; difficulty in swallowing or breathing; hoarseness) occurs (also see **section 4, Possible side effects**).

If you suffer from excessive sleepiness, your doctor should frequently monitor your degree of sleepiness. You should inform you doctor about drowsiness or sleepiness during specific activities.

Tell your doctor about all of your medical conditions, including if you:

- have a history of mental health problems, including psychosis
- have heart problems including, for example, angina (chest pain), previous heart attack, enlarged heart
- have high blood pressure or your high blood pressure is controlled by medicines
- are taking hormonal contraceptives
- have a history of drug or alcohol abuse or addiction
- have liver or kidney problems.

NUVIGIL can be abused or lead to dependence. Keep NUVIGIL in a safe place to prevent misuse and abuse. Selling or giving away NUVIGIL may harm others, and is against the law. Tell your doctor if you

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have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Children and adolescents:

Children and adolescents younger than 18 years should not take NUVIGIL.

Other medicines and NUVIGIL:

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take NUVIGIL with the following medicines:

- A hormonal birth control method, such as birth control pills, shots, implants, patches, vaginal rings, and intrauterine devices (IUDs). Hormonal birth control methods may not work while you take NUVIGIL. Women who use one of these methods of birth control may have a higher chance of getting pregnant while taking NUVIGIL, and for two months after stopping NUVIGIL. You should use effective birth control while taking NUVIGIL and for two months after your final dose. Talk to your doctor about birth control choices that are right for you while taking NUVIGIL.
- Medicines to treat epilepsy (e.g. carbamazepine, oxcarbamazepine, phenobarbitone or phenytoin).
- Medicines for tuberculosis (e.g. rifabutin and rifampicin).
- St. John’s wort.
- Antiviral medicines to treat HIV infection (protease inhibitors e.g. indinavir, nelfinavir, saquinavir or ritonavir).
- Antibiotics (e.g. clarithromycin, erythromycin, chloramphenicol).
- Medicines to treat fungal infections (e.g. ketoconazole, itraconazole).
- Medicine for the treatment of acute seizures and for inducing sedation and amnesia before medical procedures such as midazolam.

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- Ciclosporin (used to prevent organ transplant rejection, or for arthritis or psoriasis).
- Medicines for mental disorders such as bipolar mood disorder (e.g. quetiapine) or anxiety (e.g. diazepam).
- Calcium channel blockers or beta-blockers for high blood pressure or heart problems (e.g. amlodipine, verapamil or propranolol).
- Omeprazole (for acid reflux, indigestion or ulcers).
- Medicines for depression (e.g. MAO inhibitors such as e.g. selegiline and moclobemide).
- Medicines for thinning the blood (e.g. warfarin). Your doctor will monitor your blood clotting times during treatment.

NUVIGIL with food, drink and alcohol:

NUVIGIL can be taken with or without food but should rather be taken on an empty stomach to avoid a delayed onset of action.

You should avoid drinking alcohol. It is not known how drinking alcohol will affect you when taking NUVIGIL.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking NUVIGIL.

Pregnancy:

You should not take NUVIGIL during pregnancy.

NUVIGIL is suspected to cause birth defects if taken during pregnancy.

Talk to your doctor about the birth control methods that will be right for you while you are taking

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NUVIGIL (and for two months after stopping) or if you have any other concerns.

A woman should have two reliable pregnancy tests showing negative one week apart, before commencing NUVIGIL.

Breastfeeding:

You should not take NUVIGIL if you are breastfeeding your baby.

Driving and using machines:

People with sleep disorders should always be careful about:

- getting involved in activities that could harm them or other people
- taking decisions that could have serious consequences to them or their stakeholders.

NUVIGIL can cause dizziness.

It is not always possible to predict to what extent NUVIGIL may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which NUVIGIL affects you.

NUVIGIL contains lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NUVIGIL.

3. HOW TO TAKE NUVIGIL:

Do not share medicines prescribed for you with any other person.

Always take NUVIGIL exactly as your doctor has told you. Check with your doctor or pharmacist if you

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are not sure.

The usual dose of NUVIGIL is:

For narcolepsy: 150 mg or 250 mg once daily in the morning.

Your doctor may reduce the dose of NUVIGIL if you have severe hepatic impairment.

Your doctor may reduce the dose of NUVIGIL if you are elderly.

Your doctor will tell you how long your treatment with NUVIGIL will last. Do not stop treatment early because you feel more alert. If you have the impression that the effect of NUVIGIL is too strong or too weak, tell your doctor or pharmacist.

Swallow the tablet whole with a little water.

Take your dose before food as food can slow down the rate at which the treatment enters your blood stream and may delay the effects of your medicine.

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If you take more NUVIGIL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of an overdose of NUVIGIL may include:

- Trouble sleeping
- Restlessness
- Confusion
- Feeling disorientated
- Feeling excited
- Hearing, seeing, feeling or sensing things that are not really there (hallucinations)
- Nausea and diarrhoea
- A fast or slow heartbeat
- Chest pain
- Shortness of breath
- Increased blood pressure.

If you forget to take a dose of NUVIGIL:

Do not take a double dose to make up for forgotten individual doses.

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4. POSSIBLE SIDE EFFECTS:

NUVIGIL can have side effects.

Not all side effects reported for NUVIGIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUVIGIL, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking NUVIGIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting (dizziness).

These are all very serious side effects. If you have them, you may have had a serious reaction to NUVIGIL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- mental (psychiatric) symptoms:
 - depression
 - feeling anxious
 - hearing, seeing, feeling, or sensing things that are not really there (hallucinations)
 - thoughts of suicide
 - other mental problems
 - aggressive behaviour

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- an extreme increase in activity and talking (mania)
- symptoms of a heart problem, including chest pain, abnormal heart beats, and trouble breathing
- heart attack
- a serious allergic skin reaction, including rash, hives, blisters on the skin/peeling skin called Stevens-Johnson syndrome
- life-threatening drug-induced skin reaction with skin rash, fever, lymphadenopathy, and characteristic haematologic abnormalities such as eosinophilia, thrombocytopenia, and atypical lymphocytosis

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- fatigue, thirst, influenza-like illness, pain, fever
- hayfever symptoms including itchy/ runny nose or watery eyes
- headache, dizziness
- disturbance in attention, tremor, migraine, needle and pins feeling
- difficulty sleeping
- anxiety, depression, agitation, nervousness, depressed mood
- skin reaction (dermatitis) resulting from exposure to allergens or irritants
- abnormally increased sweating.

Less frequent side effects:

- heart is beating too fast, pumping too hard
- feeling abnormal, irritable
- fits (seizures)

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- throat swelling and tightness

Side effects with unknown frequency:

- nausea, diarrhoea, dry mouth
- indigestion, stomach pain, constipation, vomiting, loose stools
- mouth sores
- increased liver enzymes
- increased heart rate
- eating disorder (anorexia), loss of appetite
- excessive or abnormally large production or passage of urine
- shortness of breath.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE NUVIGIL:

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Protect from light and moisture.

Keep the blisters in the outer container until required for use.

Do not use after the expiry date stated on the label/carton/bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What NUVIGIL contains:

The active substance is armodafinil.

The other ingredients are: croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K29/32, pregelatinised starch.

What NUVIGIL looks like and contents of the pack:

NUVIGIL 50 mg: Round, white to off-white tablet, debossed with Cephalon 'C' on one side and '205' on the other side.

NUVIGIL 150 mg: Oval, white to off-white tablet, debossed with Cephalon 'C' on one side and '215' on the other side.

NUVIGIL 250 mg: Oval, white to off-white tablet, debossed with Cephalon 'C' on one side and '225' on the other side.

NUVIGIL tablets are available in either:

White square HDPE bottles with white child-resistant closures and an induction-sealed liner.

Clear PVC and silver aluminium blisters strips packed into outer cardboard cartons.

The available pack sizes are blister packs of 7 or 30 tablets, and HDPE bottles of 30 or 60 tablets.

Not all pack sizes may be marketed.

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Holder of Certificate of Registration:

TEVA PHARMACEUTICALS (PTY) LTD,
Maxwell Office Park,
Magwa Crescent West,
Waterfall City,
Midrand,
Gauteng,
2090
Tel: +27 11 055 0200

This leaflet was last revised in:

15 November 2024

Registration number:

NUVIGIL 50 mg: 48/1.1/1129
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Access to the corresponding Professional Information:

Website: <https://www.teva.co.za/>

The Professional Information can also be obtained from:

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Magwa Crescent West,

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